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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,746	11/20/2003	Jerry Loren McLaughlin	33724/6	8781

32642 7590 01/24/2008

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1618	

MAIL DATE	DELIVERY MODE
01/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/717,746	MCLAUGHLIN ET AL.	
	Examiner	Art Unit	
	D. L. Jones	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7,9 and 15-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7,9 and 15-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 11/15/07 wherein claims 1-6, 8, and 10-14 were canceled and claims 7, 9, and 15 were amended.

Note: Claims 7, 9, and 15-24 are pending.

APPLICANT'S INVENTION

2. Applicant's invention is directed to methods of preparing crude extracts as set forth in independent claims 7, 9, 15, and 20.

RESPONSE TO APPLICANT'S ELECTION

3. Applicant's election of Group I (claims 7, 9, and 15-24) in the reply filed on 11/15/07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Note #1: Applicant is respectfully requested to cancel the non-elected subject matter. It should be noted that

Note #2: Elected Group I is directed to methods of preparing crude extracts according to independent claim 7, 9, 15, and 20 comprising obtaining one or more acetogenin compound(s) from the genus Asimina.

NEW MATTER REJECTION

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 7, 9, and 15-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Review of the originally filed claims of the instant invention disclose that the plant part was a twig, unripe fruit, seed, bark, or some other bioactive plant part (it should be noted that the other bioactive plant part was not set forth). However, the amended claims are directed broadly to 'one or more plant parts' which is not set forth in the instant specification. If Applicant is in disagreement with the Examiner, it is respectfully requested that Applicant point to page and line number wherein support may be found for the claims.

112 SECOND PARAGRAPH REJECTIONS

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 7, 9, and 15-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7, line 7: The claim as written is ambiguous because of the awkward claim language in the phrase 'drying the one or more to form a mass'. Did Applicant intend to insert 'plant parts' after 'more'?

Claims 7, 9, and 15-24: The claims as written are ambiguous because of the phrase 'removing the water layer from the crude extract layer to form the crude extract' (see claim 7, lines 15-16, for example). Specifically, if one has a crude extract, then the removal of water does not form the crude extract because it is already present. Thus, it is suggested that the phrase be written as follows: 'removing the water layer from the crude extract, the resulting crude extract...compound'.

Claim 7, 9, and 15-24: The claims as written are ambiguous because of the phrase 'placing the mass in a sieve to form a sieved product' (see independent claim 7, line 8, for example). Specifically, it is unclear how a sieved product is generated by placing it in a sieve. In other words, in order to obtain a sieved product, 'shaking' or 'filtering' must occur. Thus, it is respectfully suggested that the phrase be replaced with 'separating the mass using a sieve to form a sieved product'.

Claims 7, 9, and 15-24 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are those relating to how Applicant performs the standardizing of the crude extract to obtain zero percent moisture and an LC50 of 0.5 ppm in a BST..

103 REJECTIONS

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 7, 9, and 15-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ratnayake et al (Evaluation of the pawpaw tree, Asimina triloba (Annonaceae), as a commercial source of the pesticidal annonaceous acetogenins, 1993, pages 644-648) in view of McLaughlin et al (US Patent No. 5,717,113).

Ratnayake et al disclose the evaluation of the pawpaw tree, asimina triloba (Annonaceae), as a commercial source of pesticidal annonaceous acetogenins (see entire document, especially, page 1, first complete paragraph). The methodology of Ratnayake et al involves unripe fruits being frozen and freeze-dried while the seeds were air dried at room temperature (corresponds to Applicant's step (a)). The other plant materials were dried in an oven (corresponds to Applicant's steps (a) and (b)). All of the plant materials were ground in a Wiley mill (corresponds to Applicant's steps (c) and (d)) [page, 2, third complete paragraph]. The dried plant materials were then repeatedly extracted with 95% ethanol (corresponds to Applicants part (e) and (f)). The

combined extract was evaporated under reduced pressure to provide a syrupy residue (corresponds to Applicant's step (g)). The syrupy residue was transferred to a separatory funnel with a mixture of water and chloroform (corresponds to Applicants step (h)). After removal of the chloroform, the water layer was then extracted several times with chloroform and the combined layers were reduced under vacuum (corresponds to Applicant's step (i)). The extract was eventually analyzed by the brine shrimp lethality bioassay (BST) (corresponds to Applicant's step (j)). Based upon the results of the brine shrimp lethality of the extract for the various plant parts extracted and tested, the twigs, unripe fruit, seeds, root wood, and all the stem bark samples had LC50 values ranging from 0.042 to 0.104 ppm (page 3, fourth complete paragraph). Ratnayake et al fail to disclose spray drying the crude extract onto an inert carrier to facilitate encapsulation or tableting.

McLaughlin et al disclose bioactive acetogenins and derivatives which were isolated from Asimina triloba. The substantially pure acetogenins and acetogenin derivatives exhibit cytotoxicity to human solid tumor cell lines and exhibit effective pesticidal activities (see entire document, especially, abstract). In addition, McLaughlin et al disclose that the compounds may be formulated into pharmaceutical compositions in dosage forms and administered orally to those in need of oncolytic therapy (column 4, lines 9-19). The pharmaceutical compositions may be formulated in dosage forms for oral administration in a capsule, a gel seal, or a tablet. The capsules may include any well known pharmaceutically acceptable material such as gelatin or cellulose derivatives. The tablets may be formulated with convention procedures by compressing

mixtures of the active acetogenins and solid carriers, and lubricants well known to those in the art. The compounds may also be administered in the form of a hard shell tablet or capsule containing lactose or mannitol and a conventional filler and tableting agent.

Thus, while Applicant and Ratnayake et al disclose the making of a crude extract as set forth in independent claims 15 and 20, Ratnayake et al neither disclose that its crude extract is suitable for administration to a human nor that its crude extract may be spray dried on an inert carrier to facility encapsulation or tableting as set forth in independent claims 7 and 9 and dependent claims 18and 23. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Ratnayake et al using the teachings of McLaughlin et al and formulate the crude extract into a pharmaceutical composition for oral administration because both Ratnayake et al and McLaughlin et al disclose acetogenin compounds isolated from Asimina triloba. In addition, McLaughlin et al disclose that while their pure acetogenins and acetogenin derivatives exhibit effective pesticidal activities (note that Ratnayake et al also discloses that their crude extract exhibits pesticidal activities), their (McLaughlin et al) invention also exhibits cytotoxicity to human solid tumor cell lines. As a result, McLaughlin et al disclose that the acetogenin compounds may be formulated into dosage forms using pharmaceutically acceptable carriers for oral administration to patients in need of oncolytic therapy (column 4, lines 15-19). Specifically, McLaughlin et al disclose that the pharmaceutical compositions may be in dosage forms such as capsules, a gel seal, or tablet. The capsules may comprise any well known pharmaceutically acceptable material and the tablets may be formulated in accordance

with conventional procedures by compressing mixtures of the active acetogenins and solid carriers, and lubricants well known in the art. In addition, McLaughlin et al disclose that their acetogenin compounds may also be administered in the form of a hard shell tablet or capsule containing lactose or mannitol as a binder and conventional fillers and tableting agents (columns 4-5, bridging paragraph). Therefore, since both Ratnayake et al and McLaughlin et al disclose acetogenins from the genus Asimina, references are considered to be within the same field of endeavor. Thus, the reference teachings are combinable.

Note: Both Ratnayake et al and McLaughlin et al were previously mailed to Applicant. However, a copy of Ratnayake et al is included with this office action.

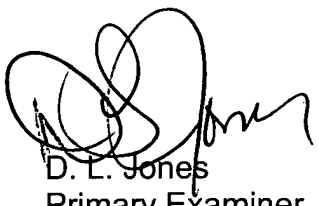
COMMENTS/NOTES

11. Review of the provisional application (60/428,602) only disclose the plant part, twigs. Thus, the appearance of the phrase the priority data of the instant invention as it relates to 'twig' goes back to the provisional data. However, for other plant parts, the data is the filing data of the instant application, since it was first that 'unripe fruit', 'seeds' and 'bark' were disclosed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



D. L. Jones
Primary Examiner
Art Unit 1618

January 18, 2008